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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,140	10/06/2003	Weiniu Gan	CL001165DIV	1062
25748	7590	09/07/2006	EXAMINER HALVORSON, MARK	
CELERA GENOMICS ATTN: WAYNE MONTGOMERY, VICE PRES, INTEL PROPERTY 45 WEST GUDE DRIVE C2-4#20 ROCKVILLE, MD 20850			ART UNIT 1642	PAPER NUMBER

DATE MAILED: 09/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/678,140

Applicant(s)

GAN ET AL.

Examiner

Mark Halvorson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 24-38 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,37 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3 and 24-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-3 and 24-38 are pending.

Claims 1, 2, 37 and 38 have been withdrawn.

Claims 3 and 24-36 are under examination.

35 USC § 101 rejection withdrawn

1. The rejection of claims 3, 24-36 for lacking utility is withdrawn in view of Applicant's persuasive arguments.

35 USC § 102(b) rejections maintained

2. Claims 3, 24-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Hayward et al. (WO-98/53061-A1, published 11/26/1998).

Claim 3 is drawn to an isolated antibody that selectively binds to a polypeptide, wherein the amino acid sequence of said polypeptide consists of SEQ ID NO: 2. Claim 24 is drawn to an isolated antibody that selectively binds to a polypeptide, wherein the amino acid sequence of said polypeptide comprises SEQ ID NO: 2. Claim 25 further limits claim 3, and claim 26 further limits claim 24, wherein the antibody of the respective base claim is a monoclonal antibody. Claim 27 is drawn to claim 3, claim 28 is drawn to claim 24, claim 29 is drawn to claim 25, and claim 30 is drawn to claim 26, wherein the antibody is coupled to a detectable substance. Claim 31 is drawn to claim 3, claim 32 is drawn to claim 24, claim 33 is drawn to claim 25, and claim 34 is drawn to

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claim 26, a composition comprising an antibody and a pharmaceutically acceptable carrier. Claim 35 is drawn to an isolated antibody fragment that selectively binds to a polypeptide, wherein the amino acid sequence of said polypeptide consists of SEQ ID NO: 2, and wherein the antibody fragment comprises a fragment selected from the group consisting of: an Fab fragment, an F(ab')₂ fragment, and an Fv fragment. Claim 36 is drawn to an isolated antibody fragment that selectively binds to a polypeptide, wherein the amino acid sequence of said polypeptide comprises SEQ ID NO: 2, and wherein the antibody fragment comprises a fragment selected from the group consisting of: an Fab fragment, an F(ab')₂ fragment, and an Fv fragment.

Hayward et al. in WO-98/53061-A1 (page 70, SEQ ID NO: 7) teach an antibody that binds to a polypeptide that has 98.9% homology to the instant SEQ ID NO: 2 (see Exhibit A of April 21, 2006 Office Action). Hayward et al. also teach a monoclonal or polyclonal antibody or fragments of antibodies such as Fab fragments (page 23, lines 27-28). Furthermore, Hayward et al. teach the antibody coupled to fluorescent compounds (page 27, lines 19-20) and a pharmaceutically acceptable carrier (page 28, lines 277-29).

Applicant argues that in order for Hayward et al's antibody to anticipate the antibody of the instant application Hayward's antibody must necessarily bind to the peptide of SEQ ID NO: 2 of the instant application. Applicant argues that Hayward's antibody does not necessarily selectively bind the peptide of SEQ ID NO:2 because of the difference in the amino acid sequence between Hayward's peptide and the peptide of SEQ ID NO:2.

Applicant's arguments have been fully considered but they are not persuasive. Hayward et al's peptide is identical to the 615 amino acid peptide of SEQ ID NO: 2 except for a 6 amino acid deletion in the C terminus of Hayward et al's peptide (see Exhibit A of the April 21, 2006 Office Action. Therefore, it is the Examiner's position that Hayward et al's antibody is directed to the same antigen that the claimed antibody binds. One of ordinary skill in the art would reasonably conclude that Hayward et al's antibody also possesses the same structural and functional properties as those of the antibody claimed and, therefore, it appears that Hayward et al's antibody is identical to the claimed antibody. Since the Patent and Trademark Office does not have the facilities for examining and comparing the claimed antibody and Hayward et al's antibody, the burden of proof is upon the Applicants to show an unobvious distinction between the structural and functional characteristics of the claimed antibody and the antibody of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

Furthermore, as stated in the Office Action of April 21, 2006, the Specification as originally filed reasonably communicates that the limitation "selectively binds" means that the antibody not only binds to a polypeptide consisting of SEQ ID NO: 2 but also binds to a polypeptide with some degree of variance. The specification states that

An antibody is still considered to selectively bind a peptide even if it also binds to other proteins that are not substantially homologous with the target peptide so long as such proteins share homology with a fragment or domain of the peptide target of the antibody. In this case, it would be understood that antibody binding to the peptide is still selective despite some degree of cross-reactivity. (page 28 2nd paragraph)

Thus, Hayward et al's antibody would reasonably read on Applicant's claims 3 and 24-36 using Applicant's definition of the limitation "selectively binds"

Summary

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

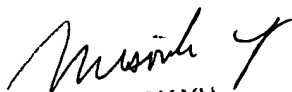
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson, PhD whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the

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examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Halvorson, PhD
Patent Examiner
571-272-6539


MISOOK YU
PRIMARY EXAMINER